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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,742

10/06/2005

Deborah Addison

JJM0620USPCT

3713

28977 7590 05/27/2009  
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EXAMINER

JACKSON, BRANDON LEE

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,742	<b>Applicant(s)</b> ADDISON ET AL.	
	<b>Examiner</b> BRANDON JACKSON	<b>Art Unit</b> 3772	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 5-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is in response to amendments/arguments filed 4/16/2009. Currently, claims 1-2 and 5-15 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/16/2009 has been entered.

#### ***Response to Arguments***

Applicant's arguments, see Page 4, filed 4/16/2009, with respect to claim 1-2 and 5-15 have been fully considered and are persuasive. The rejection of 7/24/2008 has been withdrawn. The rejection is withdrawn because Kirkwood is excluded under 103(c).

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Applicant should say "no part of the therapeutic agent contact the wound surface after the device has been applied to the wound" because any structurally equivalent device would teach that

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limitation because the therapeutic agent would not contact the wound surface if it is merely not applied to a wound. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. How the aperture is opened by the wound exudate, but not contacting the therapeutic agent even though the point of the of the device is to have the apertures opened by the exudate so the therapeutic agent may pass into the wound to treat it is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant states that the apertures are opened by exudate and the therapeutic agent is made liquid by the exudate in order to pass through the aperture to the wound surface to treat it. Applicant needs to further explain how this may happen while maintaining that no part of the therapeutic agent contacts the wound surface after the apertures are opened.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinecke (US Patent 4,499,896) in view of Arnold (U.S. Patent 5,759,570).

Heinecke discloses a wound treatment device (15) comprising a water impermeable (cols. 5-6, lines 60-7) envelope (19) having one aperture (18) in the envelope (19), wherein the aperture is between .01 and 1 sq-cm (col. 10, lines 31-32). The envelope (19) is formed of flexible sheet material because it has to expand and contract with the amount of fluid in the envelope (19). Heinecke fails to disclose a degradable material blocking the apertures, a therapeutic agent behind the degradable material and dispersed in a bioerodile substance, and a microorganism-impermeable container.

Arnold discloses a wound dressing (1) comprising a water-impermeable envelope (col. 3, lines 49-54). The envelope contains a slow release therapeutic substance (col. 5, lines 4-6) that is released in the presence of wound fluid (col. 4, lines 22-25). The layer containing the therapeutic substance, dispersed on the wound contact layer, is degradable or bio-absorbable and contains collagen and glycosaminoglycans (col. 4,

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lines 52-53), which also provides a substrate for the enzymes to act upon. The wound dressing (1) also contains microbicide, such as chlorhexidine and maintains a sterile environment for the wound (col. 4, lines 10-14). The wound dressing (1) container is impermeable to micro-organisms (col. 3, lines 58-60). No portion of the therapeutic substance (col. 5, lines 4-6) contacts that wound surface when the dressing is not applied to a wound. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Heinecke device to have therapeutic agent and degradable material blocking the aperture, as taught by Arnold, in order to allow therapeutic agent to be released into the wound, which aids in the rapid healthy healing of the wound. The therapeutic agent (col. 5, lines 4-6) would be larger than the aperture, as taught by Heinecke, because the substance defines a whole layer of the device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/  
Examiner, Art Unit 3772

BLJ

/Michael Brown/

Primary Examiner, Art Unit 3772